

“Serious Adverse Events: Challenges and new ideas”

Mon 23 March 2015, 2:00 - 4:45pm

An afternoon meeting organised by the
Medical Section of the Royal Statistical Society (RSS)

Venue: RSS HQ, Errol St, London EC1Y 8LX
(entrance on Lamb's Buildings)

PROGRAMME

This programme includes talks by people with extensive experience in collecting and evaluating data on Serious Adverse Events (SAE) associated with drugs and non-pharmaceutical interventions. Contexts range from observational studies of 'harms', routinely collected data to RCTs within regulatory frameworks. They will introduce some of the practicalities and challenges in this area, and present new ideas for evaluation and for analysis and presentation of SAE data, as stimulus for discussion.

Talks

Prof Yoon Loke (University of East Anglia. Consultant physician and co-convenor of the Cochrane Adverse Effects Methods Group):

“If nothing happens, is everything all right?” Distinguishing genuine reassurance from a false sense of security.”

An overview and special problems in measuring and reporting Serious Adverse Events in RCTs and in observational studies

Prof Barney Reeves (University of Bristol, on behalf of the development group for ACROBAT-NRSI):

“ACROBAT-NRSI: a new tool for assessing the risk of bias in non-randomised studies of the harms of interventions”

Introduction of a tool to assess ‘Risk of Bias’ in non-randomised studies of interventions and, in particular, its application to non-randomised studies evaluating adverse effects of interventions.

Dr Harry Southworth (Data Clarity Consulting Ltd, Freelance consulting statistician):

“Statistical Analysis of Cumulative Serious Adverse Event Data in Development Safety Update Reports”

A simple approach to ranking SAEs to give regulators a consistent and structured approach to reviewing large amounts of data .

Discussion

Costs: There is no cost to attend, but it would be useful if you register in advance to allow planning for refreshments

Registration: Email Dr Gill Price at gill.price@uea.ac.uk

RSS HQ

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Travel Information: The RSS headquarters are located near the Barbican Centre. The nearest tube stations are Moorgate, Old Street, Liverpool Street and Barbican.
